AGREEMENT FOR CLINICAL SERVICES

Randomized, Open-Label, Multicenter Trial of the Safety and Effectiveness of Oral Telithromycin (Ketek®) and Amoxicillin/Clavulanic Acid (Augmentin®) in Outpatients With Respiratory Tract Infections in Usual Care Settings

between

AVENTIS PHARMACEUTICALS INC.
Bridgewater, New Jersey

and

PPD DEVELOPMENT, LLC.
3151 South 17th Street
Wilmington, NC 28412

Dated 1 November 2001
CMD #2327

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LISTING OF ATTACHMENTS

AGREEMENT FOR CLINICAL SERVICES

THIS AGREEMENT FOR CLINICAL SERVICES ("Agreement") is entered into as of this 1st day of November, 2001 between PPD Development, LLC, a contract research organization with its principal place of business at 3151 South 17th Street, Wilmington, NC 28412 (hereinafter referred to as "PPD"), and Aventis Pharmaceuticals Inc., a corporation with its principal place of business at Rt 202/206, P.O. Box 6800, Bridgewater, NJ 08807-0800 (hereinafter referred to as "AVENTIS").

WITNESSETH:

WHEREAS, AVENTIS is engaged in the development, manufacture, distribution, and/or sale of pharmaceutical products; and

WHEREAS, PPD is a contract research organization engaged in the business of managing and executing clinical research programs; and

WHEREAS, AVENTIS wishes to retain PPD to perform certain clinical research services ("the Project") in connection with a clinical trial AVENTIS is conducting ("the Study") pursuant to a protocol entitled, "A MultiCenter Study of Single Escalating Dose Safety and Pharmacokinetics of Oral Fexofenadine Hydrochloride in Children from 6 months to 2 years of Age", a copy of which is attached as Attachment A and is incorporated by reference herein ("the Protocol").

WHEREAS, PPD is willing to perform such services in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, for valuable consideration and intending to be legally bound, the parties agree as follows:

1. DEFINITIONS

As used in this Agreement, the following terms have the meanings set forth below.

1.1 "Critical Activities" shall mean the unit-based services and deliverables for the Project.

1.2 "Critical Activity Billing Unit" means, with respect to any Critical Activity, the level or amount of services, which this Agreement specifies as constituting one unit of such Critical Activity.

1.3 "Evaluable Patient" shall mean a patient who has met all Protocol entrance criteria, is randomized to treatment, and has data available for analysis in accordance with the Protocol.

1.4 "FDA" shall mean the United States Food and Drug Administration.

1.5 "IND" shall mean a claimed Investigational New Drug Exemption filed with the FDA.

1.6 "Investigator" shall mean a licensed health professional who is engaged by PPD or AVENTIS to conduct the Study.

1.7 "Investigator Meeting" means a meeting to familiarize participating Investigators with the protocol requirements.

1.8 "NDA" shall mean a New Drug Application.

1.9 "Randomized Patient" shall mean a patient who has met all Protocol entrance criteria and is randomized to treatment in accordance with the Protocol.

1.10 "Study Drug" shall mean Telithromycin

1.11 "Aventis" means the sponsor and/or Contract Partners, who provide services for Aventis in performance of the work under this Agreement including potentially Quintiles, Inc. (hereinafter referred to as "QKAN").

2. SCOPE OF PPD RESPONSIBILITIES

Set forth in Attachment B (Scope of Work) is a description of the specific activities, which PPD shall perform for each of the Critical Activities.

3. PERSONNEL

3.1 PPD Staff Qualifications. PPD will perform its work hereunder with highly qualified, trained and educated personnel knowledgeable in Good Clinical Practices (GCPs), applicable regulatory requirements, clinical project management, pharmaceutical drug development and, if possible, in AVENTIS therapeutic areas and products. PPD is responsible for training of its staff in order to maintain their knowledge to the state of the art. The costs for such training will be fully covered by PPD.

3.2 Key Project Personnel. AVENTIS considers personnel described in Attachment C (Key Personnel), which is attached hereto and hereby incorporated by reference as "Key Personnel" for the Project. As long as these persons remain in the employ of PPD respectively, they shall not be replaced in the Project or their Project responsibilities materially reduced or altered without the prior agreement of AVENTIS which shall not be unreasonably withheld.

3.3 Staff Member Termination. PPD will terminate immediately the assignment of any PPD staff member working under the Agreement for reasonable cause identified by the AVENTIS Clinical contact named in Attachment C (Key Personnel).

3.4 Assignment and Subcontracting. PPD may not assign or subcontract any part of the work under this Agreement to any third party unless AVENTIS has specifically agreed in writing to such assignment or subcontract.

3.5 During the period in which the Study is being conducted, neither party shall recruit, hire or employ any personnel of the other who is material to the performance of the Study without the prior written consent of the other party.

4. TRANSFER OF OBLIGATIONS

4.1 Pursuant to 21 CFR312.52, AVENTIS has transferred to PPD all of the obligations identified in Attachment D (Transfer of Obligations), attached hereto and hereby incorporated by reference, and agrees that the same description and extent of obligations transferred shall be included in Form FDA 1571, Section 13. PPD agrees to carry out diligently all transferred obligations.

5. FINANCIAL TERMS AND CONDITIONS

5.1 Total Budget. The Project Budget is attached hereto as Attachment E (Project Budget). In accordance with the Project Budget, AVENTIS agrees to pay PPD a maximum of $28,865,896 ($19,384,796 for Direct Costs and $9,481,100 for Indirect Costs) incurred for the duration of the Project. The Project Budget (Attachment E) is fully transparent and includes all planned Project Activities and all planned costs. Pass through costs are estimates and may vary as circumstances require provided however Aventis shall approve pass through expenditures in excess of that set forth above. AVENTIS shall not be responsible for paying PPD any labor costs or for reimbursing PPD for any pass-through or third-party costs incurred other than those set for in Attachment E (Project Budget), except as AVENTIS shall expressly agree upon in accordance with Section 5.3 (Unforseen Costs).

Amounts payable to PPD with respect to Attachment E (Project Budget), excluding travel and other pass-through or third party costs shall be billed on the basis of the Payment Schedule, Attachment F. Invoices will be sent monthly according to the Fixed Payments within of the Payment Schedule. The Variable Payments will be invoiced when the variable trigger, as identified within the Payment Schedule, is achieved, and in the event the trigger is not achieved will be prorated using the set forth unit price within the Variable Payment portion of the Payment Schedule. The Payment Schedule contains an additional $500,000 incentive for patients in excess of 20,000. The additional $500,000 will be available only when PPD exceeds 20,000 patients and will be invoiced on a prorated basis using the set forth unit price within the Variable Payment portion of the Payment Schedule. Subject to section 5.3, the Payment Schedule is the total amount payable to PPD for the successful performance of the parameters identified within the Payment Schedule, Attachment F and Scope of Work, Attachment B.

5.2 Payment Based on Critical Activities. Amounts payable to PPD with respect to this Project, excluding travel and other pass-through expenses (such as payments to Investigators and other third parties), shall be billed on the basis of the successful performance of the Critical Activities identified in Attachment B (Scope of Work).

5.3 Unforeseen Costs. In the event that, after the initiation of the Project, AVENTIS shall require a material change in the scope of work to be performed by PPD hereunder, the parties shall execute a project change form substantially in the form of Attachment G (Change Order) hereto. The Change Order shall specify the amount of direct and indirect costs (including pass-through and third party) which shall be added or deleted from the Project Budget as a result of the change in scope of Project.

5.4 Travel/Pass-Through Reimbursement. Travel and other pass-through expenses reasonably incurred by PPD in connection with the performance of the Project and which have been provided for in the Project Budget shall be reimbursed to PPD within thirty (30) days of receipt by AVENTIS of an itemized statement listing all such expenses, together with any appropriate supporting documentation. In situations where expenses incurred by PPD may also be allocated to PPD's other customers (e.g., a site visit to an institution participating in the Study and a clinical study sponsored by one or more of PPD's other customers), PPD shall bill AVENTIS for only its equitable portion of such expenses. Whenever possible, PPD shall manage its activities on behalf of AVENTIS and its other customers in such a fashion so as to maximize the opportunity for the sharing of expenses.

In order to receive reimbursement for any pass-through expenses, PPD must provide a copy of a written receipt for any expense of twenty-five dollars ($25.00) or more. Specific prior approval shall be obtained for any expense of two hundred and fifty dollars ($250.00) or more. PPD will not be asked to initiate work before such approval is given. PPD will conform to AVENTIS's Vendor Travel Policy (Attachment H) attached hereto and incorporated herein by reference.

It is expressly understood that all pass-through expenses shall not have profit, overhead or general administration factors applied to them and shall be separately accounted for by PPD. Any savings due to under-spending in Investigator grants or laboratory charges may not be applied to labor or other pass-through costs without the prior written approval of AVENTIS.

5.5 Monthly Payments PPD will invoice AVENTIS according to Attachment F (Payment Schedule) for work performed as outlined in the Attachment B (Scope of Work). AVENTIS will not pay for any section of an invoice, which contains disputed amounts. Any disagreement between AVENTIS and PPD regarding work performed or expenses incurred by PPD and specified on the invoice must be resolved in full before that portion of the invoice will be paid by AVENTIS. AVENTIS will not pay for any time or expense incurred by PPD in reconciling invoices. In the event of a dispute regarding an invoice, AVENTIS shall pay the undisputed portion and the parties shall negotiate in good faith in an effort to resolve promptly such dispute. In no event shall AVENTIS be obligated to pay any invoices, which are received more than ninety (90) days after completion or termination of the Project.

5.6 Financial Audits. AVENTIS, or its auditors, may audit any financial records of PPD associated with this Agreement upon 48 hours notice until two years after completion or early termination of the Study. Such records may include, without limitation, invoices from third parties, contracts with third parties and payments relating to the Study. To the extent such records are not separable from other customer records, PPD shall grant reasonable access to the records to an independent auditor selected by AVENTIS. In no event shall such auditors be entitled to disclose to AVENTIS any information relating to projects for PPD's other customers. In the event it is determined that PPD has overcharged AVENTIS for any pass-through expenses, PPD shall promptly reimburse AVENTIS for the amount of such overcharge.

6. PROJECT MANAGEMENT

6.1 Performance Metrics. PPD understands that the study described herein is a pivotal study for AVENTIS and, therefore, AVENTIS associates a high level of risk in achieving the NDA/MAA filing date established by corporate mandate by

contracting out the activities described in this Agreement. Accordingly, in the event that PPD does not provide clean case report forms, including all queries with appropriate resolution for all patients, to AVENTIS within sixty (60) days of the date the last patient completes treatment (28 February 2002), in accordance with Attachment I (Project Time and Events Schedule), AVENTIS shall be entitled to deduct from the compensation payable to PPD hereunder an amount documented by AVENTIS to be reasonably necessary to cover the costs of internal resources, and associated travel and other out-of-pocket expenses which AVENTIS reasonably allocates or incurs to obtain clean case report forms, including all queries with appropriate resolution for all patients, on time. The foregoing shall not apply to the extent PPD can establish that the failure to provide clean case report forms, including all queries with appropriate resolution for all patients, by the deadline is the result of events which were beyond the control of PPD and which could not have been avoided by the exercise of reasonable diligence.

6.2 Mutually Acceptable Solution. In the event the Project falls behind schedule, PPD shall propose, and the parties shall endeavor to agree upon, a mutually acceptable solution to bring the Project back onto schedule or to take whatever other action is required to remedy the problem. AVENTIS will not be responsible for reimbursing PPD for any costs or expenses incurred in accordance with this Article 6 unless such delay is a product of Force Majeure or unless agreed to per Section 5.3 (Unforeseen Costs). For the avoidance of doubt, nothing in this Article 6 is intended to limit or prevent AVENTIS from exercising its rights under Section 6.1 (Performance Metrics) or Article 11 (Term and Termination of Agreement) hereof.

6.3 Performance Obligations. PPD will perform all work hereunder in accordance with the terms of the Protocol, all written directions and instructions from AVENTIS, generally accepted professional standards of care and all applicable federal, state and local laws, rules and regulations of each country where the Study will be conducted, including without limitation Good Clinical Practices and ICH Guidelines for Clinical Practice.

7. CONFIDENTIALITY

7.1 Confidentiality of Information. PPD agrees to hold in confidence all materials, documents and information that AVENTIS discloses to PPD or an Investigator pursuant to this Agreement, and all materials, documents and information gathered or developed pursuant to this Agreement ("Confidential Information").

7.2 Use of Confidential Information. PPD will use such Confidential Information only for the purpose of fulfilling its obligations and exercising its rights under this Agreement and will not disclose it, without the prior written consent of AVENTIS, to any third party except for PPD's employees, Investigators, IRB members and others who have a need to know such information in order to perform the Project and are bound in writing by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. The obligations of confidentiality hereunder shall continue for a period of ten (10) years from the date the Confidential Information is disclosed or developed. PPD's obligations of confidentiality hereunder shall not apply to information that PPD can establish:

(a) is in the public domain at the time of disclosure or development;

(b) is published or otherwise becomes part of the public domain after disclosure or development through no fault of PPD, an Investigator or their respective employees or agents;

(c) was in the possession of PPD at the time of disclosure or development, as established by contemporaneous written records, and was not acquired directly or indirectly from AVENTIS under an obligation of confidence; or

(d) is independently developed by PPD without use of or reliance on any Confidential Information.

7.3 Disclosure Required by Law. In the event that PPD is required by law to disclose any Confidential Information, PPD will, as soon as possible (and in any event prior to such disclosure), notify AVENTIS of such requirement so that AVENTIS may seek a protective order or other appropriate remedy, or in its sole discretion, waive compliance with this Section 7.3. In the event that no such protective order or other remedy is obtained, or in the event that AVENTIS waives compliance with this Section 7.3, PPD will furnish only that portion of the Confidential Information which it is advised by counsel it is legally required to furnish and will exercise all reasonable efforts to obtain reasonable assurance that confidential treatment will be accorded the Confidential Information so furnished.

7.4 Availability of Injunctive Relief. PPD acknowledges that the disclosure of Confidential Information without AVENTIS's express written permission will cause AVENTIS irreparable harm, and that the breach or threatened breach of the non-disclosure and/or non-use provisions of this Agreement will entitle AVENTIS to injunctive relief, in addition to any other legal or equitable remedies that may be available to it.

ATTACHMENT D

Transfer of Obligations

As permitted by 21 CFR 312.52, the following obligations of the SPONSOR will be transferred from AVENTIS to PPD DEVELOPMENT:

1. 21 CFR 312.32:
   PPD Development will promptly inform AVENTIS of any important safety information, including serious or unexpected adverse experiences received by PPD Development. AVENTIS will retain responsibility for FDA and other Regulatory Agency notifications.

2. 21 CFR 312.53:
   PPD Development will select monitors qualified by training and experience to monitor the progress of the Project.

3. 21 CFR 312.53:
   PPD Development will select Investigators qualified by training and experience and Aventis or designee will notify FDA of selection."

4. 21 CFR 312.53:
   PPD Development will procure the following documents from each Investigator to be monitored by PPD Development:
   a. A completed and signed Form FDA-1572.
   b. Current curriculum vitae of the principal Investigator and all other individuals identified on Form FDA-1572.
   c. Protocol signed by the principal Investigator.
   d. A copy of the informed consent form to be used by the Investigator.
   e. Institutional Review Board approval of the Protocol and informed consent form including Board membership list and license number.
   f. As appropriate, Institutional Review Board approval of Protocol amendments and annual re-approvals.
   g. Disclosure Agreement and Clinical Investigation Agreement signed by the principal Investigator.

5. 21 CFR 312.55:
   PPD Development will provide all participating Investigators with current Study Drug Package Insert and, as the Project proceeds, keep each participating Investigator informed of new information received from AVENTIS regarding the Study Drug.

6. 21 CFR 312.56:
   PPD Development will report to AVENTIS any Investigator that is not complying with his/her signed agreement (Form FDA-1572), end the Investigator's participation in the Project upon instruction from AVENTIS, and recover unused Study Drug.

7. 21 CFR 312.56:
   PPD Development will monitor the progress of the Project in accordance with this Project Contract, Monitoring Guidelines issued under 21 CFR 10.90 and the applicable Project SOP's.

8. PPD Development will summarize the evidence related to the safety of the Study Drug as it is obtained from the Investigators being monitored by PPD Development and make sure evidence available to AVENTIS.

9. 21 CFR 312.59:
   PPD Development will assure the proper return of all unused supplies, as specified in the applicable Project SOP's, of Study Drug, from each PPD Development monitored Investigator whose participation in the Project is completed or terminated.

10. 21 CFR 312.57 & 21 CFR 312.58:
    PPD Development will retain records and reports associated with the Project in accordance with cited CFR and the applicable Project SOP's, and comply with any FDA or other Regulatory Agency inspections and/or requests.